IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

BENJAMIN P. SALVIO, Individually and as Administrator of the Estate of JANINE M. TRAGESSER, Deceased,	)	
Plaintiff,	)	
	)	**2:11-cv-00553**
vs.	)	
	)	
AMGEN, INC., a Delaware Corporation; IMMUNEX, INC., a wholly owned subsidiary of AMGEN, INC.; WYETH, LLC, a Delaware corporation; and PFIZER, INC., a Delaware corporation,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER OF COURT

Pending before the Court is Defendants' MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(B)(6) (Document No. 18) with Memorandum of Law in Support of Defendants' Motion to Dismiss Plaintiff's First Amended Complaint for Failure to State a Claim Pursuant to Fed. R. Civ. P. 12(b)(6) (Document No. 19); Plaintiff's Opposition to Motion to Dismiss Pursuant to FRCP 12(b)(6) and MOTION TO AMEND (Document No. 20); and a Reply in Support of Defendants' Motion to Dismiss Plaintiff's First Amended Complaint for Failure to State a Claim (Document No. 21). Accordingly, the motions are now fully briefed and ripe for disposition.

Factual Background[1]

The present case arises from the death of Janine M. Tragesser ("Decedent") on May 13, 2010. (Compl. at 2:55-6.) Subsequent to Ms. Tragesser's death, on July 26, 2010, the Orphans' Court of Westmoreland County, Pennsylvania, appointed her son, Benjamin P. Salvio ("Plaintiff"), as administrator of her estate. (Compl. at 2:57-9.) Plaintiff has filed an eight-count

[1] All facts alleged by Plaintiff in her Complaint are taken as true for the purpose of the motion to dismiss.

Amended Complaint against four (4) pharmaceutical companies ("Defendants" collectively) for the death of his mother, alleging that Defendants Amgen, Inc., Immunex, Inc.,[2] Wyeth, LLC, and Pfizer, Inc.,[3] are responsible. (*See* Compl. at 3-4:93-101). Plaintiff claims that Defendants were "engaged in the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical products, including Enbrel, throughout the United States and internationally[.]" (Compl. at 2-3.) Plaintiff further claims that Defendants failed to "adequately disclose the true health consequences, risks, and side effects which result from the ingestion of this drug, including the risk of fatal fungal infections" which can lead to death. (Compl. at 7-8:192-4.) He also claims that Defendants' warnings about the risks of taking Enbrel were not only materially false, but also misleading and incomplete. (Compl. at 8:213-4.)

Enbrel hit consumer markets on or about November 2, 1998. (Compl. at 6:156-7.) After its introduction into the market, Defendants began receiving reports of a number of adverse effects afflicting patients taking Enbrel. (Compl. at 6:158-9.) These include, but are not limited to: "serious infections requiring hospitalizations, infections leading to death, increased tuberculosis, increased rates of cancer, including cancer in teenage patients, and congestive heart failure." (Compl. at 6:159-61.) Furthermore, within the first five (5) months on the market, post-marketing reports documented thirty (30) individuals who suffered from serious infections, including six (6) deaths, stemming from the use of Enbrel. (Compl. at 6:163-4.) A large portion of these cases occurred in patients who already had one or more potential risk factors of infections, including diabetes, active infections, or a history of chronic recurrent infections. (Compl. at 6:165-7.)

[2] Immunex, Inc. is owned by Amgen, Inc.

[3] Pfizer, Inc. is the successor in interest to Wyeth, LLC. The Court does not reach Pfizer's argument that it is not a proper Defendant because Decedent's use of Enbrel preceded its acquisition of Wyeth, LLC.

Decedent first became aware of Enbrel[4] through "direct-to-consumer" media advertising and, no later than 2005, she asked her doctor to prescribe Enbrel to alleviate the pain caused by her rheumatoid arthritis. (Compl. at 4:115-9.) Decedent's doctor prescribed Enbrel to her in 2005.[5] At an unspecified date, apparently after years of taking the drug, she developed mucormycosis,[6] a fungal infection of the sinuses, brain, and lungs, which frequently affects individuals who have weak immune systems, or diabetes, which weakens an individual's immune system. (Compl. at 5:122-5.) The Complaint reflects that no one ever informed Decedent that taking Enbrel could cause such an infection. (Compl. at 5:132-3.) It further alleges that the mucormycosis caused the Decedent to experience "significant respiratory problems" which "severely damag[ed] her lungs, making it painful and difficult even to talk[.]" (Compl. at 5:124-6.) During her illness, Decedent made over twenty (20) hospital visits, incurring medical bills for her treatment totaling over 2.5 million dollars. (Compl. at 5:127-8.)

In 2008, three (3) years after Decedent began taking Enbrel, the Federal Drug Administration ("FDA") made the Defendants "strengthen [the] 'black box' warning about infections, including serious infections leading to hospitalization or death that have been observed in patients treated with Enbrel." (Compl. at 5:129-32.) Subsequent to the strengthening of the "black box" warning, Decedent continued to suffer from the debilitating effects of the mucormycosis, as well as a number of other severe medical problems, and had "a very poor quality of life[.]" (Compl. at 5:136-7.) Plaintiff avers that if Decedent had been informed about these side effects of Enbrel prior to her being prescribed the drug, she would not have taken it.

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[4] Enbrel, a biological product, reduces chemicals in the body which affect the inflammatory and immune system responses. (Compl. at 6:151-3.) Specifically, Enbrel "inhibits the action of tumor necrosis factor (TNF), a component of the body's natural defenses against serious infections." (Compl. at 6:154-5.)

[5] Defendants state that Decedent began taking Enbrel in 2001. (Document No. 19 at 3.) However, the Complaint reflects that she began taking the drug in 2005. (Compl. at 4:117-9.)

[6] Also known as zygomycosis. (Compl. at 5:122.)

(Compl. at 5:132-5.)

In anticipation of the Defendants "taking responsibility" for Decedent's medical problems, she entered into a tolling agreement, which permitted the Defendants to review her medical records and contentions from February 24, 2010, until March 28, 2011. (Compl. at 5:138-41.) Sadly, on May 13, 2011, Decedent passed away from complications related to her medical condition, which the Complaint states is directly related to her having taken Enbrel. (Compl. at 5:142-3.)

The Complaint states the following causes of action against all Defendants: (1) negligence; (2) strict products liability (design and failure to warn); (3) breach of express warranty; (4) breach of implied warranty; (5) gross negligence/punitive damages and; (6) a wrongful death claim. (Compl. at 10-17.) Plaintiff also brings a survival action. (Compl. at 17-9.) However, Plaintiff's wrongful death claim and survival action are mechanisms by which Plaintiff can bring this action, based upon the underlying claims articulated above. Defendants, in response, assert the following defenses: (1) Plaintiff's strict liability and breach of warranty claims are not cognizable under Pennsylvania law; (2) Plaintiff failed to state a claim for negligence because of insufficient pleadings and because the Enbrel Package Insert specifically warned that Enbrel had a side effect of infection; (3) Plaintiff's failed to state a claim for gross negligence/punitive damages due to insufficient pleadings; and (4) because all claims should be dismissed, Plaintiffs wrongful death claim and survivor action should be dismissed because they cannot stand by themselves. (*See* Document No. 19.)

Standard of Review

A motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) challenges the legal sufficiently of the complaint filed by Plaintiff. The United States Supreme Court has held that "[a] plaintiff's

obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 555 (207) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)) (alterations in original).

The Court must accept as true all well-pleaded facts and allegations, and must draw all reasonable inferences therefrom in favor of the plaintiff. However, as the Supreme Court made clear in *Twombly*, the "factual allegations must be enough to raise a right to relief above the speculative level." *Id.* The Supreme Court has subsequently broadened the scope of this requirement, stating that only a complaint that states a ***plausible*** claim for relief survives a motion to dismiss." *Ashcroft v. Iqbal*, -- U.S. --, 129 S. Ct. 1937, 1950 (2009) (***emphasis added***).

Thus, after *Iqbal*, a district court must conduct a two-part analysis when presented with a motion to dismiss for failure to state a claim. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the Court must separate the factual and legal elements of the claim. *Id.* Although the Court "must accept all of the complaint's well-pleaded facts as true, [it] may disregard any legal conclusions." *Id*. at 210-211. Second, the Court "must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.' In other words, a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." *Id*. at 211 (citing *Iqbal* 129 S. Ct. at 1949). The determination for "plausibility" will be "'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" *Id*. at 211 (quoting *Iqbal* 129 S. Ct. at 1950).

As a result, "pleading standards have seemingly shifted from simple notice pleading to a more heightened form of pleading, requiring a plaintiff to plead more than the possibility of

relief to survive a motion to dismiss." *Id.* at 211. That is, "all civil complaints must now set out 'sufficient factual matter' to show that the claim is facially plausible. This then 'allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Id*. at 210 (quoting *Iqbal*, 129 S. Ct. at 1948).

However, nothing in *Twombly* or *Iqbal* changed the other pleading standards for a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) and the requirements of Fed. R. Civ. P. 8 must still be met. *See Phillips v. Co. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (internal citations omitted). Fed. R. Civ. P. 8 requires a showing, rather than a blanket assertion, of entitlement to relief, and "contemplates the statement of circumstances, occurrences, and events in support of the claim presented and does not authorize a pleader's bare averment that he wants relief and is entitled to it." *Twombly*, 550 U.S. at 555 n.3 (internal citations and quotations omitted). Additionally, the Supreme Court did not abolish the Fed. R. Civ. P. 12(b)(6) requirement that "the facts must be taken as true and a complaint may not be dismissed merely because it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on those merits." *Phillips*, 515 F.3d at 231(citing *Twombly*, 550 U.S. at 553).

Legal Analysis

As a preliminary matter, the Court notes that jurisdiction in this case rests on the diversity of the parties. 28 U.S.C. § 1332(a). Pursuant to 28 U.S.C. § 1332(a), district courts "have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest, and is between . . . citizens of different States." *Id.* Complete diversity requires that, in cases with multiple plaintiffs or multiple defendants, no plaintiff be a citizen of the same state as any defendant. *See Zambelli Fireworks Mfg. Co. v. Wood*, 592 F.3d 412, 419 (3d Cir. 2010).

Further, a federal court sitting in diversity must apply the substantive law of the state in which it sits, *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938), including its choice of law rules, *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941). All parties presume that Pennsylvania law applies to this case, as will the Court.

Defendants contend that the Complaint should be dismissed in its entirety. The Court will address each cause of action advocated by Plaintiff.

I. Documents Considered on Judicial Review

Before considering the claims set forth by Plaintiff, the Court must determine whether to consider a document submitted by Defendants, specifically the Enbrel Package Insert. (*See* Document Nos. 19-1, 19-2.)[7] To resolve a Fed. R. Civ. P. 12(b)(6) motion, a court may generally consider the allegations in the complaint, along with any exhibits attached to the complaint and matters of public record. *See Moore v. Watson Pharms. Labs,* No. 01-4260, 2002 U.S. Dist. LEXIS 636, at *3 (E.D. Pa. Jan. 15, 2002); *U.S. Express Lines Ltd. V. Higgins*, 281 F.3d 383, 388 (3d Cir. 2002); *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 259 (3d Cir. 1998). Furthermore, the United States Court of Appeals for the Third Circuit has made it clear that "a court may consider any undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document" without converting a motion to dismiss into one for summary judgment. *Pension Benefit Guar. Corp. v. White Consol. Industries*, 998 F.2d 1192, 1196 (3d Cir. 1993) (internal citations omitted) (further stating a plaintiff with a legally deficient claim cannot survive a motion to dismiss simply by failing to attach a dispositive document on which he relied).

[7] Document No. 19-1 is a copy of the Enbrel Package Insert, whereas Document No. 19-2 is two copies of that same document with different issue dates, the first has the same issue date as Document No. 19-1, January 2001, and the second is dated August 2001. (*See* Document Nos. 19-1, 19-2.) No post-2001 language for the Enbrel Package Insert has been provided to the Court.

Neither party disputes the authenticity of the attached document. Furthermore, Plaintiff makes reference to, and thus incorporates by reference, the Enbrel Package Insert in his Complaint, stating "Defendants purposely ignored and/or understated the risk of such serious infections . . . due to Enbrel's use in its labels, ***package inserts***, advertisements, marketing and other promotional materials." (Compl. at 7:173, 12:318-9.) (***emphasis added***); *See Adamson v. Ortho-McNeil Pharm., Inc.*, 463 F. Supp. 2d 496, 499-501 (D.N.J. 2006) (stating that package insert containing warnings could be considered by the court at the motion to dismiss stage). Thus, the Court's reading of the Complaint "is informed by [the] [document] . . . of which [it] can take judicial notice." *City of Pittsburgh*, 147 F.3d at 259. The actual warning provided by Defendants is central to Plaintiff's "failure to warn" claim. Accordingly, the Court will consider the Package Insert in ruling on Defendants' motion to dismiss pursuant to Rule 12(b).

II. Negligence

Plaintiff's first claim against Defendants is a negligence claim. (Compl. at 10-12:259-332.) Plaintiff avers that "Defendants had a duty to Plaintiff and other consumers of their drug to exercise reasonable care in order [to] properly design, manufacture, produce, test, study, inspect, mix, label, market, advertise, sell, promote and distribute this product." (Compl. at 11:265-8.) The Complaint contains a vague laundry list of fifteen (15) generalized alleged breaches of duty. However, Plaintiff fails to specifically allege what type of negligence theory he is pursuing.

As an initial matter, Plaintiff seems to bring a claim on the basis of negligent failure to test and negligent marketing. However, Pennsylvania does not recognize claims for negligent failure to test or negligent marketing. (*See* Document No. 19 at 11.) *See Viguers v. Philip Morris USA, Inc.*, 837 A.2d 534, 541 (Pa. Super. 2003) ("negligent failure to test" is not a viable cause of action recognized by our courts.); *Wolfe v. McNeil-PPC, Inc.*, No. 07-348, 2011 U.S. Dist.

LEXIS 34714, *17 (E.D. Pa. Mar. 30, 2011) (stating that Pennsylvania does not recognize a tort for negligent marketing.). Thus, the Court will only consider Plaintiff's negligence claim under failure-to-warn and design/manufacture theories.

Under Pennsylvania law, in order for Plaintiff to state a claim for negligence under either a failure-to-warn or design/manufacture theory, he must show: "that the manufacturer owed a duty to the plaintiff; that the manufacturer breached that duty; and such breach was the proximate cause of plaintiff's injuries." *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 749 (W.D. Pa. 2004) (citing *Dauphin Deposit Bank & Trust v. Toyota*, 596 A.2d 845, 849-50 (Pa. Super. 1991); *Oddi v. Ford Motor Co.*, 234 F.3d 136, 144 (3d Cir. 2000). Furthermore, in a negligence claim, as opposed to a strict liability claim, Plaintiff must prove that the manufacturer was at fault. *See Parkinson*, 315 F. Supp. 2d at 749.

In a products liability case involving a pharmaceutical drug, Pennsylvania courts have adopted the "learned intermediary doctrine" and have stated:

> [T]he manufacturer of a prescription drug known to be dangerous for its intended use, has a duty to exercise reasonable care to inform those for whose use the article was supplied of the facts which make the product likely to be dangerous. However, the warnings which are required to be given by the manufacturer must be directed to the physician, not the patient-consumer. This is so because it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug. The warnings which must accompany such drugs are directed to the physician rather than to the patient-consumer as it is for the prescribing physician to use his independent medical judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug. Thus, in an action against a drug manufacturer based upon inadequate warnings, the issue to be determined is whether the warning, if any, that was given to the prescribing physicians was proper and adequate.

Daniel v. Wyeth Pharms., Inc., 15 A.3d 909, 924 (Pa. Super. 2011) (quoting *Taurino v. Ellen*, 579 A.2d 925, 927 (Pa. Super. 1990), *appeal denied*, 527 Pa. 603, 589 A.2d 693 (1991)). Thus, by warning a consumer's physician, the manufacturer will have discharged its duty to the consumer.

A. Negligent Failure-to-Warn

In regard to his failure-to-warn claim, Plaintiff alleges, *inter alia*, that Defendants permitted Enbrel to be sold without adequate warnings, as well as ignoring and/or understating the infection risk to those taking Enbrel. (Compl. at 11:278-302.) Other than a vague reference that the FDA demanded a "strengthened" black box warning in 2008, Plaintiff does not describe the alleged failure-to-warn. Plaintiff also does not describe the differences between the "black box" warning on the Enbrel package before and after the FDA's demand.[8] Nor does Plaintiff plead sufficient facts about the timing of Decedent's use of Enbrel, the onset of her infection, or how the alleged distinctions in the warnings would have had a causal effect.

Furthermore, Plaintiff specifically recognized in the Complaint that Enbrel contained a Package Insert, and it appears to be undisputed that throughout the entire relevant period, the Enbrel package had with it the twenty-five (25) page Package Insert. The Package Insert outlined different warnings and adverse effects which may occur when taking Enbrel. (*See* Document No. 19-2.) Enbrel's Package Insert, in effect in 2001 (prior to the FDA demand) identified infections as the primary risk of taking Enbrel. The warning, which is located at the beginning of the Package Insert and is in large type, warns of the following:

> **WARNINGS: INFECTIONS: IN POST-MARKETING REPORTS, *SERIOUS INFECTIONS AND SEPSIS, INCLUDING FATALITIES*, HAVE BEEN REPORTED WITH THE USE OF ENBREL. MANY OF THE**

[8] Although Plaintiff contends that the "black box" warning was strengthened in 2008, neither party has provided the post-2008 language to the Court.

> **SERIOUS INFECTIONS HAVE OCCURRED IN PATIENTS ON CONCOMITANT IMMUNOSUPPRESSIVE THERAPY THAT, IN ADDITION TO THEIR UNDERLYING DISEASE COULD PREDISPOSE THEM TO INFECTIONS. RARE CASES OF TUBERCULOSIS (TB) HAVE BEEN OBSERVED IN PATIENTS TREATED WITH TNF ANTAGONISTS, INCLUDING ENBREL. PATIENTS WHO DEVELOP A NEW INFECTION WHILE UNDERGOING TREATMENT WITH ENBREL SHOULD BE MONITORED CLOSELY. ADMINISTRATION OF ENBREL SHOULD BE DISCONTINUED IF A PATIENT DEVELOPS A SERIOUS INFECTION OR SEPSIS. TREATMENT WITH ENBREL SHOULD NOT BE INITIATED IN PATIENTS WITH ACTIVE INFECTIONS INCLUDING CHRONIC OR LOCALIZED INFECTIONS. PHYSICIANS SHOULD EXERCISE CAUTION WHEN CONSIDERING THE USE OF ENBREL IN PATIENTS WITH A HISTORY OF RECURRING INFECTIONS OR WITH UNDERLYING CONDITIONS WHICH MAY PREDISPOSE PATIENTS TO INFECTIONS, SUCH AS ADVANCED OR POORLY CONTROLLED DIABETES (see PRECAUTIONS and ADVERSE REACTIONS, Infections).**

(Document No. 19-2 at 11.) (Capitalization and bold in original, *emphasis added*) (*See* Document No. 19-2 at 13, 15-16.) Similar warnings are also located throughout the Package Insert. Plaintiff's conclusory averments that Defendants failed to adequately warn, ignored and/or understated the risks and side effects associated with the use of Enbrel, or that a prescribing doctor or customer "would not have known that for some customers, ingesting the drug could be fatal, or cause extreme illness" appear to be contradicted by the actual text of the Package Insert. (Compl. at 9:219-21.); *See* (Document No. 19-2 at 11); *Parkinson*, 315 F.Supp. 2d at 748 (stating that a pharmaceutical drug company can only be liable for a "failure-to-warn" if reasonable care is not exercised to inform those taking the drug of the dangers which come with taking the drug). At a minimum, Plaintiff has failed to plead facts regarding how this warning was not reasonable. Plaintiff has also failed to plead facts showing that Defendants did not properly discharge their duty by warning Decedents physician through the Package Insert or otherwise. He has also failed to provide any facts about how the change in the "black box" warning affected her choice to either continue taking Enbrel, or stop taking it. Without these

facts, the Plaintiff cannot sufficiently state a cause of action for lack of both breach of duty and causation. Thus, Plaintiff fails to state a claim for negligent failure-to-warn.

B. Negligent Design/Manufacture

"[T]he determination of whether a product was negligently designed turns on whether 'an alternative, *feasible*, safer design would have lessened or eliminated the injury plaintiff suffered.'" *Aaron v. Wyeth*, No. 07-927, 2010 U.S. Dist. LEXIS 14581, at * 31 (W.D. Pa. Feb. 19, 2010) (emphasis in original) (quoting *Berrier v. Simplicity Mfg.*, 563 F.3d 38, 64 (3d Cir. 2009)). Plaintiff fails to plead facts sufficient to satisfy the pleading standard in regard to an alternative, feasible, and safer design. Plaintiff does conclusorily state that Decedent would have used another treatment regimen that was safer than Enbrel (*See* Compl. at 5:134-5, 8:201, 12:326.). However, baldly stating that there are safer alternatives to Enbrel, without providing factual support that they exist, is insufficient to survive a 12(b)(6) motion. *See Leonard v. Taro Pharmaceuticals USA, Inc.*, No. 10-1341, 2010 U.S. Dist. LEXIS 127892 at *15 (W.D. Pa. Dec. 2, 2010) (stating that plaintiff failed to plead sufficient facts for negligent design of a pharmaceutical drug to show that one drug sufficiently differed from others of the same kind). Thus, because Plaintiff has failed to sufficiently plead that there exists an alternative, feasible, and safer design, the Court finds that he has failed to state a claim for negligent design/manufacture.

C. Summary of Negligence Theories

Plaintiff's recitation of specific negligent acts committed by Defendants is little more than a list of legal conclusions regarding Defendants' failure to test, market, warn, design, and manufacture. Pennsylvania law does not recognize negligent testing or negligent marketing theories. Likewise, Plaintiff's failure-to-warn theory lacks facts regarding breach of duty and

causation, and appears to be contradicted by the Enbrel Package Insert supplied by Defendants, which outlines the serious risks of infection and other adverse effects which may be caused by taking Enbrel. Furthermore, his negligent design/manufacture theory fails due to a failure to identify a safer, feasible alternative.

Thus, Defendants' Motion to Dismiss Count I of the Complaint will be **GRANTED**. Plaintiff will have leave to amend as to his negligent failure-to-warn and negligent design/manufacture claims if warranted.

III. Strict Products Liability

Plaintiff also asserts two strict product liability claims against the Defendants based on design defect and failure-to-warn theories. (Compl. at 13-14:350-76.) In his Complaint, Plaintiff avers not only that Enbrel "reached [Decedent] without substantial change in its condition," "was dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it," and that "the risks of Enbrel outweighed its utility" (Compl. at 13:339-46.), but also that Defendants "failed to warn of the true risks and dangers, and of the symptoms, scope and severity of the potential side effect[s] of the drug [Decedent] ingested." (Compl. at 13:359-61.)

Defendants argue that the strict liability claims should be dismissed because, under Pennsylvania law, strict liability claims against a pharmaceutical company for design/manufacturing defect and failure-to-warn are not cognizable. (*See* Document No. 19 at 7-9.) Rather, product liability claims against pharmaceutical companies can only be brought as negligence claims. (Document No. 19 at 7-9.) In response, Plaintiff failed to address the merits of Defendants' legal argument, and only asks the Court not to dismiss the claims because his Complaint is sufficiently pled to survive a Fed. R. Civ. P. 12(b)(6) motion. The Court agrees

with Defendants.

Product Liability claims against a pharmaceutical company, under Pennsylvania law, can only be brought under a theory of negligence, not strict liability. The Supreme Court of Pennsylvania has stated that "in cases where a failure to provide sufficient warnings relative to prescription drugs has been alleged, negligence is the only recognized basis for recovery." *Hahn v. Richter*, 673 A.2d 888, 889 (Pa. 1996). The Court further reasoned that Restatement (Second) of Torts § 402A, cmt. k (1965), which is titled "Unavoidably unsafe products," does not apply strict liability to "products such as prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings." *Hahn*, 673 A.2d at 889-90 (citing Restatement (Second) of Torts § 402A, cmt. k (1965)); *Accord Incollingo v. Ewing*, 282 A.2d 206, 219-20 (Pa. 1971) (stating strict liability was not applicable to a case involving a prescription drug manufacturer's alleged failure to properly warn physicians of the dangers involved with taking the drug); *Baldino v. Castagna*, 478 A.2d 807 (Pa. 1984) (reaffirmed that the basis for liability, when a prescription drug manufacturer failed to adequately warn of the potential dangers of the drug, was a reasonable care standard and not strict liability); *Mazur v. Merck & Co., Inc.*, 964 F.2d 1348, 1353-55 (3d Cir. 1992) (stating prescription drug manufacturer's liability is determined through a negligence theory, not a strict liability theory); *Parkinson*, 315 F.Supp. 2d at 748 (stating "that, as with inadequate warnings, the only recognized basis of liability for an improperly prepared product likewise is negligence").

In the present case, Plaintiff attempts to bring claims against a manufacturer of a prescription drug under the strict product liability theories of design defect and failure-to-warn. The Court finds and rules that Plaintiff has failed to state a cognizable strict products liability

claim under Pennsylvania law. Accordingly, Defendants' Motion to Dismiss Claims II and III of the Complaint will be **GRANTED**.[9]

IV. Breach of Express and Implied Warranties

Plaintiff claims that Defendants are also liable for breach of express and/or implied warranties. (*See* Compl. at 14-16.) Defendants respond by arguing that: (1) a pharmaceutical manufacturer cannot be held liable for claims not sounding in negligence, and (2) Plaintiff has failed to allege sufficient facts to state a claim for either breach of express or implied warranty. (*See* Document No. 19 at 9-11.) In his Brief in Opposition, Plaintiff does not address Defendants' legal arguments but contends only that the facts presented sufficiently state a claim. (*See* Document No. 20.)

As with Plaintiff's strict product liability claims, his attempt to assert claims for breach of express and/or implied warranties must fail. As noted above, the Supreme Court of Pennsylvania has ruled that a pharmaceutical manufacturer cannot be held liable for a claim that is not based in negligence. *See Hahn*, 673 A.2d at 888. Furthermore, "Pennsylvania state and federal courts have interpreted *Hahn* broadly to bar all non-negligence based claims asserted against a manufacturer of prescription drugs." *Leonard v. Taro Pharmaceuticals USA, Inc.*, No. 10-1241, 2010 U.S. Dist. LEXIS 127892, *12 (W.D. Pa. Dec. 2, 2010) (citing *Aaron v. Wyeth*, No. 07-927 2010 U.S. Dist. LEXIS 14581, *30-1 (W.D. Pa. Feb. 19, 2010) (dismissing breach of express and implied warranty claims under *Hahn*); *Kline v. Pfizer, Inc.*, No. 08-3238, 2008 U.S. Dist. LEXIS 101655, *7 (E.D. Pa. Oct. 31, 2008) (dismissing breach of express and implied warranty claims under *Hahn*); *Colacicco v Apotex, Inc.*, 432 F.Supp. 2d 514, 548 (E.D. Pa. 2006) (dismissing breach of implied warranty claim under *Hahn*)).

[9] Counts II and III are dismissed with prejudice. Amendment of these claims would be futile because strict product liability is not a proper basis for suit against a pharmaceutical manufacturer under Pennsylvania law.

Thus, the Court finds and rules that claims for breach of express and/or implied warranties against a manufacturer of prescription drugs are not cognizable under Pennsylvania law and Defendants' Motion to Dismiss counts IV and V of the Complaint will be **GRANTED**.[10]

V. Gross Negligence/Punitive Damages

In Count VI, Plaintiff asserts a claim for gross negligence and seeks punitive damages. Defendants aver that Plaintiff has failed to plead sufficient facts to support a claim for punitive damages. (Document No. 19 at 16.) Specifically, Defendants state that "Plaintiff has failed to allege how Defendants acted in such a way that was 'so outrageous as to demonstrate willful, wanton or reckless conduct.'" (Document No. 19 at 16) (citing *Hutchinson ex rel. Hutchinson v. Luddy*, 870 A.2d 766, 771 (Pa. 2005)). In response, Plaintiff argues that dismissing his punitive damages claim would be improper at this time. (Document No. 20 at 12-14.) He further argues that his punitive damages claim, as well as all of his other claims, are entitled to be tested in discovery. The Court does not find Plaintiff's argument persuasive.

In order to constitute "gross negligence," the defendants' behavior "must be flagrant, grossly deviating from the ordinary standard of care." *Tipton v. Viaquest Behavioral Health of Pa., LLC*, No. 10-3573, 2010 U.S. Dist. LEXIS 136019 at *15-16 (E.D. Pa. Dec. 23, 2010) (citing *Albright v. Abington Mem. Hosp.*, 696 A.2d 1159, 1164 (Pa. 1997)). Furthermore, "[u]nder Pennsylvania law, degrees of negligence are not generally recognized. *See Ferrick Excavating & Grading Co. v. Senger Trucking Co.*, 506 Pa. 181, 191, 484 A.2d 744, 749 (1984). Rather, the term "gross negligence" refers to a standard of care, rather than to a separate claim." *Floyd v. Brown & Williamson Tobacco Corp.*, 159 F. Supp. 2d 823, 828 (E.D. Pa. 2001). Similarly, punitive damages are not an independent cause of action, and may only be recovered

[10] Counts IV and V are dismissed with prejudice. Amendment of these claims would be futile because a breach of express and/or implied warranties is not a proper basis for suit against a pharmaceutical manufacturer under Pennsylvania law.

if there is a valid underlying claim. *See Kirkbride v. Lisbon Contractors, Inc.*, 555 A.2d 800, 802 (Pa. 1989) (stating that "[i]f no cause of action exists, then no independent action exists for a claim of punitive damage since punitive damages is only an *element* of damages. To this extent, punitive damages must, by necessity, be related to the injury-producing cause of action."). Plaintiff can only maintain this action, with an underlying injury-producing claim, if additionally, evidence of outrageous conduct exists.

> The Pennsylvania Supreme Court has also adopted the guidelines of Section 908(2) of the Restatement (Second) of Torts regarding the imposition of punitive damages: Punitive damages may be awarded for conduct that is outrageous, because of the defendant's evil motive or his reckless indifference to the rights of others. Punitive damages must be based on conduct which is 'malicious,' 'wanton,' 'reckless,' 'willful,' or 'oppressive' . . .

Nelson v. Wyeth, No. 1670, 2007 Phila. Ct. Com. Pl. LEXIS 316, at *18 (Pa. C.P. 2007) (citing *Chambers v. Montgomery*, 192 A.2d 355, 358 (Pa. 1963)). Here, Plaintiff has failed to allege conduct by any Defendant which was so outrageous as to support imposing punitive damages and the Complaint fails to satisfy the pleading standard of *Twombly, Fowler,* and *Phillips*. Furthermore, with all other claims being dismissed, Plaintiff's claim for punitive damages cannot stand alone.

It is difficult to envision facts that would support a claim for punitive damages in this case, but Plaintiff will be given an opportunity to do so. Therefore, Defendants' Motion to Dismiss Count VI of the Complaint ("gross negligence") will be **GRANTED** without prejudice.

VI. Wrongful Death Claim and Survival Action

The Complaint asserts claims for wrongful death and survival action. Wrongful death actions accrue directly to certain beneficiaries-i.e. the spouse, children, or parents--of a decedent who has been wrongfully killed. Pennsylvania's wrongful death statute states, in pertinent part: 'An action may be brought . . . to recover damages for the death of an individual caused by the

wrongful act or neglect or unlawful violence or negligence of another . . . .' Pa. C.S.A. § 8301 (2007)." *Francis v. Northumberland Co.*, 636 F. Supp. 2d 368, 393 (M.D. Pa. 2009). Furthermore, "[a]s distinguished from the wrongful death statutes, the survival statutes do not create a new cause of action; they simply permit a personal representative to enforce a cause of action which had already accrued to the deceased before his death." *McGowan v. Univ. of Scranton*, 759 F.2d 287, 295 (3d Cir. 1985). Plaintiff's wrongful death claim and survival action are legitimate as mechanisms for recovery. They cannot be brought, however, as claims in-and-of themselves, because an underlying claim, such as negligence, is needed for these claims to be cognizant. *See id.* Thus, because Defendants' Motion to Dismiss will be **GRANTED** as to counts I-VI**,** Defendants' Motion to Dismiss Plaintiff's wrongful death claim will also be **GRANTED** without prejudice, dependent on Plaintiff's ability to sufficiently plead negligence in his second amended complaint. Likewise, Plaintiff's survival action is not available until he has sufficiently pled a cause of action. Without an underlying claim, his survival action is moot. *See id.*

Leave to Amend the Complaint

If a complaint is subject to Rule 12(b)(6) dismissal, a district court must permit a curative amendment unless such an amendment would be inequitable or futile. *Alston v. Parker*, 363 F.3d 229, 235 (3d Cir. 2004); *accord Grayson v. Mayview State Hosp.*, 293 F.3d 103 (3d Cir. 2002). A district court must provide the plaintiff with this opportunity even if the plaintiff does not seek leave to amend. *Id.* In this case, Plaintiff has requested leave to amend, and Defendants do not oppose that request. The district court may dismiss the action if the plaintiff does not file a second amended complaint within that time, or if the plaintiff files a notice of his intent to stand on the complaint as filed.

Plaintiff's non-negligence claims are barred as a matter of law and it would be futile and inequitable to permit further amendments as to those causes of action. However, Plaintiff's negligence claim is potentially cognizable, although the Court has determined that insufficient facts have been pled to render the claim plausible at this time. Accordingly, Plaintiff shall have leave to amend the Complaint a second time to correct technical errors and to clarify legal and factual assertions in support of a negligence claim, including punitive damages, if warranted. If Plaintiff chooses to amend, it will be essential to plead facts that there was a safer product on the market in regard to his design/manufacturing defect claim, and to overcome the learned intermediary doctrine. *See Parkinson,* 315 F.Supp. 2d at 748-9; *Makripodis v. Merrell-Dow Pharmaceuticals, Inc*., 523 A.2d 374, 378 (Pa. Super. 1987).

Defendants have raised numerous meritorious legal challenges. If Plaintiff chooses to file a second amended complaint, it will be important to address all of these alleged shortcomings to assure that the amended complaint contains sufficient factual allegations to render the claim(s) "plausible" in compliance with the pleading standard set forth and explained in *Twombly*, *Fowler* and *Phillips*.

Conclusion

In summary, Defendants' Motions to Dismiss the Complaint will be **GRANTED** in all respects. Plaintiff's Motion to Amend will be **GRANTED** in part.

An appropriate Order follows.

McVerry, J.

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

BENJAMIN P. SALVIO, Individually and as Administrator of the Estate of JANINE M. TRAGESSER, Deceased,	)	
Plaintiff,	)	
	)	**2:11-cv-00553**
vs.	)	
	)	
AMGEN, INC., a Delaware Corporation; IMMUNEX, INC., a wholly owned subsidiary of AMGEN, INC.; WYETH, LLC, a Delaware corporation; and PFIZER, INC., a Delaware corporation,	)	
Defendants.	)	

ORDER OF THE COURT

AND NOW, this 18th day of August, 2011, for the reasons set forth in the foregoing Memorandum Opinion, it is hereby **ORDERED, ADJUDGED and DECREED** that Defendants' MOTION TO DISMISS (Document No. 18) is **GRANTED**; and Plaintiff's MOTION TO AMEND (Document No. 20) is **GRANTED IN PART**, as follows: Plaintiff may file an amended complaint on or before September 1, 2011, to correct technical errors and clarify the legal and factual assertions in support of a negligence claim, including punitive damages if warranted, or he may elect to stand on his original complaint as filed.

BY THE COURT:

/s/ Terrence F. McVerry
United States District Court Judge

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